

The Office carries the initial burden of establishing a *prima facie* case of obviousness, and in doing so must establish: (1) that there exist some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings; (2) that there is a reasonable expectation of success that can be derived by such a combination; and (3) that the references when combined teach or suggest all of limitations of the claims. Recently, the Federal Circuit has stated that the evidence of a teaching, suggestion, or motivation to combine references must be "clear and particular." See *In Re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). For the reasons that will be discussed below, the combination of references relied upon by the Examiner do not provide the motivation or reasonable expectation of success to support a *prima facie* case of obviousness.

In its analysis, the Office has failed to properly take into consideration the limitation that requires D-tagatose to be administered in an amount to "selectively" induce production of butyrate or "selectively" stimulate growth of Lactobacilli and lactic acid bacteria in the human colon. Even when the Office Action at page 2 reviews the content of the pending claims, the "selective" limitation is read out of the claims like it was not even there. The issue presented by the claimed invention is not whether the prior art provides both motivation and predictability of success of administering D-tagatose to induce production of butyrate or stimulate the growth of Lactobacilli and lactic acid bacteria, but whether it provides the motivation and expectation of success for "selectively" inducing production of butyrate and "selectively" stimulating the growth of Lactobacilli and lactic acid bacteria.

Neither Mortensen et al. nor MacFarlane et al., alone or in combination, teach or suggest that the administration of D-tagatose will produce the selective effects recited in the claims. While it may be generally recognized in the prior art that monosaccharides and ketohexoses may serve as a substrate for the production of short chain fatty acids, and have been associated with the growth of certain bacteria, these teachings do not remotely resemble a clear and particular motivation to use D-tagatose to produce the selective effects recited in the claims. As has been pointed out in the past, Mortensen et al. clearly shows (Figures 1 and 2) that there is a lack of predictability of the amounts of various short chain fatty acids that are produced in vitro by several mono- and disaccharides.

Similarly, the teachings of Morelli and Zehner may lead a person of ordinary skill in the art to expect some degradation of D-tagatose in the human colon, but this does not provide a clear and particular motivation to select D-tagatose to produce the selective effects recited in the claims, and does not provide any predictability that these claimed effects would occur.

The teachings of the prior art relied upon in the final Office Action may make it obvious to select any saccharide to see what effects would occur, but a mere "obvious to try" rationale is insufficient to establish a *prima facie* case of obviousness, particularly when it is coupled (as here) with an utter lack of predictability of achieving the recited selective effects. See *In re Yates*, 211 USPQ 1149, 1151 (CCPA 1981).

Although the Office addresses the "selective" limitation in the claims on page 5 of the Office Action, the teachings of Mortensen et al. to the effect that a substantial capacity for enhancement of short chain fatty acid production, specifically butyrate, is

available when sufficient amounts of an appropriate substrate are present does not provide the clear and particular motivation or suggestion that D-tagatose is such an appropriate substrate or would provide the claimed selective effects. The mere fact that D-tagatose may not be alone with respect to its ability to selectively enhance the production of butyrate is irrelevant to the question of whether the prior art provides a sufficient teaching and provides predictability that D-tagatose will produce this enhanced effect. Accordingly, since the references relied upon by the Office fail to establish a *prima facie* case of obviousness, the Office is requested to withdraw this ground of rejection.

Prompt and favorable reconsideration of this application is respectfully submitted.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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